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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,915	06/29/2006	Raghupathi Kandarapu	GEN 3.3-008	2317
45776 7590 08/30/2010 DR. REDDY'S LABORATORIES, INC. 200 SOMERSET CORPORATE BLVD SEVENTH FLOOR BRIDGEWATER, NJ 08807-2862				
EXAMINER				
LOVE, TREVOR M				
ART UNIT		PAPER NUMBER		
1611				
NOTIFICATION DATE		DELIVERY MODE		
08/30/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patpros@drreddys.com

Office Action Summary

Application No.

10/596,915

Applicant(s)

KANDARAPU ET AL.

Examiner

TREVOR M. LOVE

Art Unit

1611

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 June 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 4-8, 12-18 and 21-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 4-8, 12-18 and 21-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Acknowledgement is made to Applicant's response filed 06/10/2010.

Claims 1, 4-8, 12-18, and 21-24 are pending.

Claims 2, 3, 9-11, 19, and 20 are cancelled.

Claims 1, 12, and 18 are currently amended.

Claims 1, 4-8, 12-18, and 21-24 are currently under consideration.

New Grounds of Rejection – Necessitated by Amendment

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 4-8, 12-18, and 21-24 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 1, 12, and 18 recite "(b) a subcoating on the core..." and "(c) an acidic functional group containing enteric coating..." and the claims also recite "wherein a subcoating inhibits between active ingredient and an enteric coating" which is the broader statement of the limitation. Specifically, **first**, since a subcoating has already been identified in claims 1, 12, and 18 it is unclear if Applicant is intending to refer to an additional subcoating, or *the* subcoating already identified. For the sake of compact prosecution, the Examiner is interpreting the claim as meaning "the subcoating". **Second**, it appears that a modifier is missing before the phrase "active ingredient". As currently written, it is unclear if Applicant is intending to refer to an additional active ingredient, or *the* active ingredient already identified. For the sake of compact prosecution, the Examiner is interpreting the claim as meaning "the active ingredient". **Third**, since an enteric coating has already been identified in claims 1, 12, and 18 it is unclear if Applicant is intending to refer to an additional enteric coating, or *the* enteric coating already identified. For the sake of compact prosecution, the Examiner is interpreting the claim as meaning "the enteric coating".

Claims 4-8, 13-17, and 21-24 are rejected for depending from at least one of indefinite claims 1, 12, and/or 18.

Maintained Rejections

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 4-8, 12-18, and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Close et al (European Patent number 0094116 (A2), published Nov. 16, 1983) in view of Lassen (U.S. Patent number 4,804,669).

Close teaches therapeutic, enteric coated granules which comprise a therapeutic active core wherein said core is coated by a first coating, which is subsequently coated with an enteric coating. Said first coating comprises a dispersing aid (see claim 1). Said dispersing aid is taught as being either an alkali metal phosphate or glycine (see claim 8), said glycine is water soluble. Said dispersing aid is present in an amount of approximately 0.5 to 7.5% (see claim 1), with a preferred embodiment being taught in example II being approximately 3.5% of the entire weight of the granules. The active core is taught as being selected from a plurality of active agents, all of which have some sensitivity to acid. It is noted that the first coating of Close would inhibit interaction between the enteric coating and the active since said first coating is located between said enteric coating and said active.

Close fails to directly teach that the active is an antidepressant, as newly required in amended claims 1, 12, 18, and 21. Close further fails to teach which specific antidepressant is present, as required in claims 22-24.

Lassen teaches delivery of paroxetine to a human (see Abstract). Lassen teaches that paroxetine has "well-known anti-depressant effects" (see column 1, lines 34-40). Lassen further teaches that it can be useful to enterically coat paroxetine compositions (see column 2, lines 14-28).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the active of Lassen in the invention of Close. One would have been motivated to do so since Close is teaching a "superior time release therapeutic" which utilizes an enteric coating (see Close, Abstract), and Lassen is teaching a therapeutic that can be enterically coated. One would further have been motivated to utilize the coating method of Close since Close teaches a dispersing aid which "aid[s] in the dispersing of the enteric coating in the intestines" (see Close, page 5, lines 15-16).

Response to Arguments

Applicant argues in the remarks filed 06/10/2010 that since the actives of Close allegedly are all acidic in nature "these drugs would not be likely to react with an acidic enteric coating polymer in the solid state". Applicant's argument is not found persuasive since, in addition to providing a barrier layer between the active core and the enteric coating, the first coating also is present as a dispersing aid. It is noted that the art is not required to teach the same reasoning for adding components as Applicant, MPEP 2144 (IV) states "the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by Applicant. See, e.g., *In re Kahn*, 411 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)." Close teaches an active with two coatings, one of which is an enteric coating, wherein Lassen teaches utilizing the instant paroxetine in an enteric composition. One would have been motivated to utilize the active of Lassen

since Lassen teaches the advantageous benefits of paroxetine, which Lassen identifies as both a pain reliever and an anti-depressant. Furthermore, Lassen teaches that the paroxetine can be enterically coated, wherein Close teaches a superior coating method. The composition of Close with the active of Lassen would meet the requirements of the instant claims. Therefore, Applicant's arguments are not found persuasive. Applicant further argues that one would not be motivated to combine the teachings of Close and Lassen. Applicant's argument is not found persuasive since, as noted above, motivation for the combination clearly exists, wherein Close clearly teaches an enteric composition and Lassen teaches a method of improving enteric compositions. Further, one would be motivated to utilize the instant active in order to treat disorders wherein said active is known to be effective. It is noted that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Conclusion

No claims allowed. All claims rejected. No claims objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is

(571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/David J Blanchard/
Primary Examiner, Art Unit 1643